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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,342	05/26/2000	YUKIO KATO	046124-5025	3974
9629	7590	02/10/2005	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

JP

Office Action Summary	Application No. 09/555,342	Applicant(s) KATO ET AL.	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-17, 19-21, 25, 27, 29-33 and 35-38 is/are pending in the application.
 4a) Of the above claim(s) 11-14, 19-21, 29-31, 33, and 35-38 is/are withdrawn from consideration.
 5) ☒ Claim(s) 15, 17, 25 and 27 is/are allowed.
 6) ☒ Claim(s) 16 and 32 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant cancels claims 26,28, 34.

Accordingly, claims 15-17, 25, 27, 32 are being examined.

Claims 15, 17, 25, 27 seem to be free of prior art and are allowable.

The following are the remaining rejections.

This application contains claims drawn to an invention nonelected with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

OBJECTION

1. Claims 16, 32 are objected for the use of the language "an ezrin-like domain, a Db1 domain and a pleckstrin domain" as the sole means of identifying the domain of the protein encoded by the claimed DNA, because different laboratories may use the same laboratory designations to define completely distinct peptide regions. Amendment of the claims to include physical and/or functional characteristics of "an ezrin-like domain, a Db1 domain and a pleckstrin domain" which unambiguously define "an ezrin-like domain, a Db1 domain and a pleckstrin domain" is required.
2. Claim 32 is objected to because claim 32 appears to be free of prior art but is objected to as being dependent upon a rejected base claim 16, but would be allowable if rewritten to be independent of claim 16.

REJECTION UNDER 35 USC 112, SECOND PARAGRAPH, NEW REJECTION

Claims 16, 32 are indefinite for the use of the language “ezrin-like”, which is a relative term, which renders the claim indefinite. The term “ezrin-like” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION

Claims 16, 32 are rejected under 35 USC 112, first paragraph, for lack of a clear written description of “an ezrin-like domain, a Db1 domain and a pleckstrin domain”.

The amended claims 16, 32 now are drawn to a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO:2, in which one to several amino acids have been deleted, substituted or added, the protein is being specifically expressed in differentiated chondrocytes, and the protein comprising an “an ezrin-like domain, a Db1 domain and a pleckstrin domain”.

The specification discloses that the ezrin-like domain of CDEP of the claimed invention has homology of 27.5% to ezrin (p.10, second paragraph). The specification discloses that the Db1 domain and pleckstrin domain (DH-PH) the Rho GEF family is necessary for Rho GEF activity, and that CDEP of the claimed invention has 22.9% homology to the DH domain of Db1 (p.11, first paragraph).

In the absence of a definition of “an ezrin-like domain, a Db1 domain and a pleckstrin domain”, and in view of the above disclosure of the specification, “an ezrin-like domain, a Db1 domain and a pleckstrin domain” encompasses variant domains of amino acids 1-374, 544-737, 764-854 of SEQ ID NO:2 with unknown structure.

The specification does not meet the 112, first paragraph written description requirement. Although drawn to DNA, the example of Lilly clearly applies here. There is no disclosure of representative species of an ezrin-like domain, a Db1 domain and a pleckstrin domain, or “structural features common to the members of the genus, which features constitute a substantial portion of the genus.” In addition, the example of Enzo also applies to the instant application as well, because the specification does not show that the claimed invention is complete “by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”

Thus one of skill in the art would conclude that Applicant does not have possession of the ezrin-like domain, Db1 domain and pleckstrin domain encoded by the claimed polynucleotide at the time the invention was made.

REJECTION UNDER 35 USC 112, FIRST PARAGRAPH, SCOPE

Claims 16, 32 are rejected under 35 USC 112, first paragraph, because while being enabled for a DNA encoding SEQ ID NO:2, the specification is not enabled for a DNA encoding a protein comprising the amino acid sequence of SEQ ID NO:2, in which

Art Unit: 1642

one to several amino acids have been deleted, substituted or added, the protein is being specifically expressed in differentiated chondrocytes, and the protein comprising an "an ezrin-like domain, a Db1 domain and a pleckstrin domain".

The specification discloses that the ezrin-like domain of CDEP of the claimed invention has homology of 27.5% to ezrin (p.10, second paragraph). The specification discloses that the Db1 domain and pleckstrin domain (DH-PH) the Rho GEF family is necessary for Rho GEF activity, and that CDEP of the claimed invention has 22.9% homology to the DH domain of Db1 (p.11, first paragraph).

In the absence of a definition of "an ezrin-like domain, a Db1 domain and a pleckstrin domain", and in view of the above disclosure of the specification, "an ezrin-like domain, a Db1 domain and a pleckstrin domain" encompasses variant domains of amino acids 1-374, 544-737, 764-854 of SEQ ID NO:2, with unknown structure.

One would not know how to make the ezrin-like domain, Db1 domain and pleckstrin domain encoded by the claimed polynucleotide in view of the unpredictability of protein chemistry, as taught by Bowie et al, Burgess et al, Lazar et al, Tao et al, and Gillies et al, all of record.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 1642

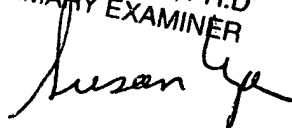
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SUSAN UNGAR, PH.D.
PRIMARY EXAMINER



Application/Control Number: 09/555,342
Art Unit: 1642

Page 7

MINH TAM DAVIS

January 28, 2005